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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	PAPER NUMBER
1646	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)
09/724,583	Saris et al.
Office Action Summary	
Examiner	Art Unit
Prema Mertz	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Apr 26, 2002 .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-56 is/are pending in the application.

4a) Of the above, claim(s) 9, 12-41, and 47-56 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-8, 10, 11, and 42-46 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I (claims 1-8, 10-11, 42-46) in Paper No. 7, 4/26/02, is acknowledged. The traversal is on the ground(s) that the restriction is improper and should be withdrawn because there is no undue burden placed upon the Examiner to search all the polynucleotides encoding the polypeptides set forth in SEQ ID NO:2, 4, 6, listed in the Restriction Requirement. This argument is not found persuasive because the searches for the 3 Groups would not overlap. Group I is directed to a nucleic acid of SEQ ID NO:1 and the special technical feature of this Group is the nucleic acid of SEQ ID NO:1. Claim 1 is an improper Markush group because it does not meet unity of invention. The different elements of a Markush group must meet unity of invention. The other nucleic acids listed in claim 1, do not share the special technical feature (SEQ ID NO:1) of Group I, because the other nucleic acids are structurally and functionally different. The proteins of SEQ ID NO:4, 6 encoded by the nucleic acids of SEQ ID NO:3, 5, are structurally different.

pm 6/24/02

Applicants argue that examining the polynucleotides encoding the polypeptides in SEQ ID NO:2, 4, 6, in one claim, would not place undue examination burden on the Examiner. However, contrary to Applicants arguments, only for EST sequence fragments, up to 10 nucleotide sequences are examined in a single application. For full-length sequences (SEQ ID NO:1) encoding full-length proteins (SEQ ID NO:2), only one sequence is examined per application.

The test for propriety of restriction is not whether the inventions are related but rather whether they are distinct and whether it would impose a burden on the examiner to search and

examine multiple inventions in a single invention. Group I-III are related as different products which are independent and distinct, each from the other, which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged.

Lastly the inventions are distinct because a search of the literature for the nucleic acid of Group I, would not be expected to reveal art for the nucleic acids of Groups II-III, which searches are extensive requiring separate searches which would be unduly burdensome.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different and recognized divergent subject matter as defined by MPEP. § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP. § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

The Groups as delineated in the restriction requirement (Paper No. 6, 3/26/02) are patentably distinct one from the other such that each invention could, by itself, in principle, support its own separate patent (as shown by the arguments put forth in the written restriction requirement).

The requirement is still deemed proper and is therefore made FINAL.

Claims 9, 12-41, 47-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed i.e. a more specific title that would identify the nucleic acid by the protein it encodes. It is suggested that the titled be amended to read approximately as follows: "nucleic acid encoding an interleukin-1 receptor antagonist-related protein".

3. The Information Disclosure Statement filed in Paper No. 6 (3/26/97), fails to comply with the provisions of MPEP § 609 because an improper form PTO-1449 or equivalent was submitted or placed in the application file. Rule 37 CFR 1.98 specifies the contents of the Information Disclosure Statement, which includes a list of all patents, publications or other information submitted for consideration by the Office, a legible copy of each publication or that portion which cause it to be listed, and all other information or that portion which cause it to be listed. 37 CFR 1.98(b) requires that each publication must be identified by author (if any), title, relevant pages of the publication, date and place of publication. The place of publication refers to name of the journal, magazine or other publication in which the information being submitted was published. To comply with this requirement, the list may not be incorporated into the specification but must be submitted in a separate paper. A separate list is required so that it is easy to confirm that applicants intend to submit an information disclosure statement and because it provides a readily available checklist for the Examiner to indicate which identified documents have been considered. Use of form PTO-1449, Information Disclosure Citation, is encouraged. Applicant is advised that the date of any re-submission of an item of information contained in a information disclosure statement or the submission of any missing

element(s) is the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements. See MPEP.. § 609 C(1-2).

pm 6/m/02 In this case, for the EMBL database submissions on the IDS, Applicants have failed to recite the name of the author and the date of publication. The Examiner has included the date of publication and the name of the author on the form PTO-1449 with the document made of record.

Claim rejections-35 USC § 112, first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4a. Claims 1-2, 4-8, 10-12, 42-46, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The deposit of biological material is considered by the Examiner to be necessary for the enablement of the current invention because the claims require availability of the deposit (see Claims 1-2). Elements required for practicing a claimed invention must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. When biological material is required to practice an invention, and if it is not so obtainable or available, the enablement

requirements of 35 USC §112, first paragraph, may be satisfied by a deposit of the material. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining ATCC Deposit No. PTA-1423 and it does not appear to be a readily available material. The ATCC deposit in full compliance with 37 CFR §§ 1.803-1.809 would satisfy the requirements of 35 USC §112, first paragraph.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or Declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and (e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-1.809 for additional explanation of these requirements.

Claims 4-8, 10-11, 42-46 are rejected under 35 U.S.C. 112, first paragraph, insofar as they depend on claims 1-2 for the ATCC number.

4b. Claims 2, 3-8, 10-11 and 42-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claims 2 and 3 are genus claims. Claim 2, sub-part (a) recites a nucleic acid molecule encoding a polypeptide "at least about 70% identical to the polypeptide as set forth in SEQ ID NO:2", which encompasses nucleic acid variants of the DNA encoding the polypeptide as set forth in SEQ ID NO:2. The term variant means a nucleic acid molecule encoding a protein having one or more amino acid substitutions, deletions, insertions and/or additions made to the DNA molecule which encodes the amino acid sequence set forth in claim 2(a). Claim 2, sub-part (b) recites "an allelic variant or splice variant of the nucleotide sequence set forth in SEQ ID NO:1". Claim 3(a)-3(e) recites nucleic acid molecules encoding various variants of the polypeptide set forth in SEQ ID NO:2. The specification and claims do not indicate what distinguishing attributes shared by the members of

the genus. The specification and claim do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to the nucleic acid molecule because claim 3 recites "at least one insertion, deletion or substitution" or a combination thereof (claim 3(e)). Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Although the specification states that these types of changes are routinely done in the art (page 20), the specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a nucleic acid encoding a protein set forth in claims 2-3 alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicants were not in possession of the claimed genus of nucleic acid molecules.

Claims 4-8, 10-11 and 42-46 are rejected under 35 U.S.C. 112, first paragraph, insofar as they depend on claims 2-3 for their limitations.

4c. Claims 2-8, 10-11, 42-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid encoding a polypeptide set forth in SEQ ID

NO:2, does not reasonably provide enablement for a nucleic acid encoding a polypeptide which is "at least about 70% identical to the polypeptide of SEQ ID NO:2" of claim 2(a) or a nucleic acid molecule encoding substitution, insertion or deletion mutants of the polypeptide set forth in SEQ ID NO:2 as recited in claim 3 (a)-(e). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 2, sub-part (a), recites "at least about 70% identical" which encompasses nucleic acid variants of the nucleotide sequence set forth in SEQ ID NO:1, which claims are overly broad, since no guidance is provided as to which of the myriad of nucleic acid molecules encoding polypeptide species encompassed by the claims will retain the characteristics of a polypeptide set forth in SEQ ID NO:2. Variants of the nucleic acid molecule encoding the IL-1ra-L polypeptide can be generated by conservative or nonconservative changes, allelic, splice species or polymorphic variants. However, Applicants have failed to disclose any actual or prophetic examples on expected performance parameters of any of the possible nucleic acid molecules encoding muteins of the IL-1ra-L polypeptide. Moreover, it is known in the art that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function. For example, Mikayama et al. (1993) teaches that the human glycosylation-inhibiting factor (GIF) protein differs from human migration inhibitory factor (MIF) by a single amino acid residue (page 10056, Figure 1). Yet, despite the fact that these proteins are 90% identical at the amino acid level, GIF is unable to carry out the function of MIF, and MIF does not exhibit GIF bioactivity (page 10059,

second column, third paragraph). It is also known in the art that a single amino acid change in a protein's sequence can drastically affect the structure of the protein and the architecture of an entire cell. Voet et al. (1990) teaches that a single Glu to Val substitution in the beta subunit of hemoglobin causes the hemoglobin molecules to associate with one another in such a manner that, in homozygous individuals, erythrocytes are altered from their normal discoid shape and assume the sickle shape characteristic of sickle-cell anemia, causing hemolytic anemia and blood flow blockages (pages 126-128, section 6-3A and page 230, column 2, first paragraph).

There is no guidance provided in the specification as to how one of ordinary skill in the art would generate a nucleic acid sequence encoding a the IL-1ra-L polypeptide other than the one exemplified in the specification. See In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. Given the breadth of claim 2, sub-part (a), claim 3, sub-parts (a)-(e), in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and

the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention.

Claims 4-8, 10-11, 42-46 are rejected under 35 U.S.C. 112, first paragraph, insofar as they depends on claims 2-3 for their limitations.

Claim rejections-35 U.S.C. 112, second paragraph

5. Claims 1-8, 10-11, 42-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 recite "hybridizes under moderately or highly stringent conditions", which are relative and conditional terms and renders the claims indefinite. Furthermore, some nucleic acids which might hybridize under conditions of specific moderate stringency, for example, would fail to hybridize at all under conditions of high stringency as recited by Applicants on page 16. The metes and bounds of the claims thus cannot be ascertained.

Claim 2 is vague in the recitation of the limitation "about 70% identical" to the polypeptide as set forth in SEQ ID NO:2. Even though the use of the term "about" in a claim is inherently vague and indefinite, its use is appropriate when employed to limit a value which is composed of indefinitely divisible units such as inches, meters, grams, and pints, where it is impractical to produce an item which has exactly the dimension recited. Even if one could practically produce an item which is exactly 1 inch in length, the length of that item is conditional upon the temperature at which it is measured. However, when defining an invention in terms of indivisible numerical units such as the

percent identity in the number of amino acids in a polypeptide or the number of legs on a chair or table, the term "about" is unacceptably vague and indefinite since it is practical to employ a term which possesses the required precision. If, for example, it is Applicant's intention that the claims should encompass a polynucleotide which is at least 70% identical to the polypeptide set forth in SEQ ID NO:2 (claim 2, sub-part (a)), then this is exactly what the claim should recite. One would not know if the term "about 70% identical" would include or exclude "50% identical" "60% identical" or even "80% identical."

Claim 2 (a), (c) and claim 3(a)-(e) recite "polypeptide has an activity of the polypeptide..." which is vague and indefinite because the activity of the polypeptide encoded by the nucleic acid being claimed, is unclear.

Claim 10 recites "other than the promoter DNA for the native IL-1ra-L polypeptide" which is vague and indefinite because it is unclear which promoter DNA is being excluded and which is being included in the claim.

Claim 46 is indefinite in the recitation of the term "fragments thereof". This language is vague and indefinite since it encompasses potentially any portion of the heterologous polypeptide including a single amino acid. There is no guidance provided as to what specific sequences the term "fragment" refers to. Therefore, the metes and bounds of the claim are unclear.

Claims 45-46 are dependent on non-elected claims 13, 14, 15, 55 or 56. It is suggested that these claims be amended to be dependant on the elected nucleic acid claims, since the nucleic acid is utilized in production of the fusion proteins.

Claim 3 recites

Claims 1-3 are improper because they recite non-elected sequences. Appropriate correction to recite only the elected sequences is requested.

Claims 4-8, 11, 42-44 are rejected as vague and indefinite insofar as they are dependant on claims 1-2 for their limitations.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6a. Claims 1-8, 10-11, 42-46, are rejected under 35 U.S.C. 102(a) as being anticipated by WO 9937662 (1999).

WO 9937662 discloses a cDNA encoding a SPOIL protein, said cDNA comprising the nucleotide sequence shown in Figure 1 (also see abstract). The reference also discloses that the cDNA encoding the protein was cloned into an expression vector, pcDNA/Amp vector, which contains a promoter operably linked to the cDNA insert encoding the SPOIL protein, as shown by the ability of the vector to be expressing a protein (pages 92-93). Host cells were transformed with the cDNA in the vector (page 92, last paragraph). Fusion proteins comprising the SPOIL proteins were also constructed using the cDNA (page 52). The BLASTX computer program was used in determining the percent identity (page 87, lines 22-27). The nucleotide sequence was cloned into a retroviral

vector MSCVneo (page 22, last 5 lines; pages 93-94). The cDNA of the reference would be capable of hybridizing under medium stringency conditions, to the polynucleotide of SEQ ID NO:1 described in the instant application. Furthermore, in the absence of an upper limit to the number of substitutions, deletions or insertions, the nucleic acid molecule disclosed in the reference meets the limitations of claim 3. Therefore, the cDNA sequence disclosed in the reference meets the limitations of the claimed nucleic acid.

6b. Claims 1-8, 10-11, 42-46 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 855 404 A1 (1998).

EP 0 855 404 discloses a cDNA encoding a IL-1ra beta protein, said cDNA comprising the nucleotide sequence shown in Figure 1 (also see abstract). The reference also discloses that the cDNA encoding the protein was cloned into an expression vector, which contains a promoter operably linked to the cDNA insert encoding the protein, as shown by the ability of the vector to be expressing a protein (pages 7-8). Host cells were transformed with the cDNA in the vector (page 7-8, last paragraph). Fusion polypeptides comprising the protein of the reference were also constructed (page 7, lines 1-8). The BLASTX, BLASTN computer programs were used in determining the percent identity (page 4, lines 34-50). The nucleotide sequence was cloned into a viral vectors (page 7, lines 52-57). The cDNA of the reference would be capable of hybridizing under medium stringency conditions, to the polynucleotide of SEQ ID NO:1 described in the instant application. Furthermore, in the absence of an upper limit to the number of substitutions, deletions or insertions, the nucleic acid

molecule disclosed in the reference meets the limitations of claim 3. Therefore, the cDNA sequence disclosed in the reference meets the limitations of the claimed nucleic acid.

6c. Claims 1-8, 10, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,075,222 (1991).

U.S. Patent No. 5,075,222 discloses a cDNA encoding a IL-1ra protein, said cDNA comprising the nucleotide sequence shown in Figure 15 (also see abstract). The reference also discloses that the cDNA encoding the protein was cloned into an expression vector, lambda GT10, which contains a promoter operably linked to the cDNA insert encoding the protein, as shown by the ability of the vector to be expressing a protein (column 27-28). Host cells were transformed with the cDNA in the vector (columns 16-17). The cDNA of the reference would be capable of hybridizing under medium stringency conditions, to the polynucleotide of SEQ ID NO:1 described in the instant application. Furthermore, in the absence of an upper limit to the number of substitutions, deletions or insertions, the nucleic acid molecule disclosed in the reference meets the limitations of claim 3. Therefore, the cDNA sequence disclosed in the reference meets the limitations of the claimed nucleic acid.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
June 24, 2002